

REMARKS

Favorable reconsideration and allowance of the claims of the present application are respectfully requested.

Claim Rejections Under 35 U.S.C. § 102(b)—Reimer et al.

Claims 1-5 and 7-11 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Reimer et al. (U.S. Patent Application Publication No. 2003/0004095, published January 2, 2003 and naming Raylene Alison Reimer et al. as “Inventors”). Specifically, the Examiner contends that Reimer et al. discloses “sweet whey permeate.”

In response, Applicants respectfully traverse this ground of rejection for at least the reasons set forth below.

The Claim Rejections Under 35 U.S.C. § 102(b) Are Improper

In regard to the pending claims, Applicants respectfully submit that Reimer et al. is not a proper reference under 35 U.S.C. § 102(b).

35 U.S.C. § 102(b) provides that “[a] person shall be entitled to a patent unless . . . the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States” (Emphasis added).

The subject application is the § 371 national stage of PCT International Application No. PCT/EP2004/007690, filed July 12, 2004, which claims priority of German Patent Application No. 103 31 202.1, filed July 7, 2003. Therefore, Applicants submit that the subject application may properly claim an effective filing date in this country of July 7, 2003.

Reimer et al. was published in this country on January 2, 2003. The publication date of Reimer et al., namely January 2, 2003, is not “more than one year prior to” an effective filing date in this country of the subject application, namely July 7, 2003, as required by 35 U.S.C. § 102(b). Therefore, Applicants respectfully submit that the claim rejections under 35 U.S.C. § 102(b) are improper. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection. However, without conceding that Reimer et al. is a proper reference under any other section of 35 U.S.C. § 102 and in the interests of compact prosecution, Applicants set forth the following remarks.

Applicants’ “Whey Permeate” Is Clearly Different from the “Caseinoglycomacropeptide” of Reimer et al.

Claim 1 of the subject application recites the language “whey permeate.” Applicants respectfully submit that “whey permeate” as recited in the pending claims differs from the “caseinoglycomacropeptide” as disclosed in Reimer et al. Specifically, Applicants enclose a mass spectroscopy analysis of a sweet whey permeate obtained by ultrafiltration as **Exhibit 1**. Applicants submit that this mass spectroscopy analysis relates to “whey permeate” as recited in the pending claims. Applicants also enclose a copy of Kim et al. (Yu-Jin Kim et al., *Purification and characterization of human caseinomacropeptide produced by a recombinant Saccharomyces cerevisiae*, 41 PROTEIN EXPRESSION & PURIFICATION 441 (2005)) as **Exhibit 2**. Applicants respectfully submit that Kim et al. relates to isolated “caseinoglycomacropeptide,” of which Reimer et al. discloses at most a partially-purified form.

The mass spectroscopy analysis of the “whey permeate” as recited in the pending claims only contains small polypeptides up to a maximum mass of about 3,000 Daltons.

However, Kim et al. disclose that the molecular mass of commercially available bovine caseinoglycomacropeptide is at least 6,500 Daltons. Kim et al., at Fig. 4(B). Therefore, Applicants respectfully submit that the enclosed papers evidence the differences between the “caseinoglycomacropeptide” of Reimer et al. and “whey permeate” as recited in the pending claims.

The Constituency of Applicants’ “Whey Permeate” and the Constituency of Reimer et al.’s “Caseinoglycomacropeptide” is Different

The second full paragraph of page eight of the subject specification as originally submitted discloses the average consistency of whey permeate, namely 84.9 % lactose, 4.5 % protein, 0.1 % fat, and 7.5 % mineral substances, with a remainder of non-separated water. In contrast, Reimer et al. discloses a preparation of “caseinoglycomacropeptide” with the following consistency: 11.7 % proteins, 81.7 % lactose, 1 % ash, 1 % lipids, with water making-up the balance. Therefore, Applicants respectfully maintain that the “caseinoglycomacropeptide” of Reimer et al. and “whey permeate” as recited in the pending claims are different.

Reimer et al. Does Not Disclose “Whey Permeate”

In regard to the language “whey permeate” as recited in the pending claims, the subject specification as originally submitted sets forth the following language in the second full paragraph of page eight:

“By way of ultrafiltration (membrane procedure, average pore size: 25 to 100 kDalton), the whey protein can be separated from whey. This ‘dewhitened’ whey consists of about 95% water and can be further processed to a powder by spray drying. This powder is herein referred to as whey permeate.” (Emphasis added)

Applicants observe that at paragraphs [0039] and [0047], Reimer et al. discloses “[s]uitable starting materials of lactic origin may include . . . a permeate of ultrafiltration of a sweet whey” (emphasis added).

Applicants respectfully submit that Reimer et al. does not disclose “whey permeate” as recited in the pending claims. Specifically, Applicants respectfully submit that the “permeate of ultrafiltration of a sweet whey” of Reimer et al. is, at most, a “suitable starting material” for producing the substances disclosed in Reimer et al. Furthermore, Applicants respectfully submit that while Reimer et al. purportedly discloses numerous formulations containing “caseinoglycomacropeptide,” Reimer et al. certainly fails to disclose formulations containing “whey permeate” as recited in the pending claims or even formulations containing a “permeate of ultrafiltration of a sweet whey,” as the Examiner has asserted. In addition, Applicants submit that Reimer et al. fails to disclose *any* data relating to the “permeate of ultrafiltration of a sweet whey.” Furthermore, Applicants submit that Reimer et al. neither explicitly nor implicitly discloses that a “permeate of ultrafiltration of a sweet whey” would be effective in treating “metabolic syndrome or type 2 diabetes or secondary diseases thereof,” as recited in the pending claims. In this regard, Applicants note that Reimer et al. merely discloses at paragraphs [0087] and [0092] that “caseinoglycomacropeptide” stimulates the release of glucagon-like peptide-1 from a “poorly differentiated caecal adenocarcinoma.” Applicants respectfully submit that this disclosure of Reimer et al. certainly does not evidence the efficacy of the Reimer et al. “permeate of ultrafiltration of a sweet whey” in treating “metabolic syndrome or type 2 diabetes or secondary diseases thereof” as required by the pending claims. In contrast to the disclosure of Reimer et al., the subject specification as originally submitted discloses *in vivo* data both in rats and humans at pages 16-29, for example.

In view of the foregoing, Applicants respectfully submit that Reimer et al. does not disclose “whey permeate” as recited in the pending claims. Therefore, Applicants respectfully submit that Reimer et al. does not anticipate claims 1-5 and 7-11. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Claims 6 and 12-14 Are Novel

The Examiner did not reject claims 6 and 12-14 as allegedly anticipated by Reimer et al. Accordingly, Applicants agree that at least claims 6 and 12-14 are novel.

Claim Rejections Under 35 U.S.C. § 103(a)—Reimer et al.

Claims 1-14 are rejected under 35 U.S.C. § 103(a) as allegedly obvious over Reimer et al. The Examiner set forth her purported rationale on pages 3-4 of the September 1, 2010 Office Action.

In response, Applicants respectfully traverse the rejection, for at least the reasons set forth below.

Reimer et al. Does Not Teach Or Suggest “Whey Permeate”

As discussed above, Applicants respectfully submit that Reimer et al. does not disclose “whey permeate” as recited in the pending claims. For at least the reasons set forth above, Applicants submit that Reimer et al. neither teaches nor suggests “whey permeate” as recited in the pending claims.

Applicants Disclosed Unexpected Results

Applicants respectfully submit that the subject application as originally submitted discloses unexpected results relative to the prior art. Specifically, the subject specification discloses the following unexpected results:

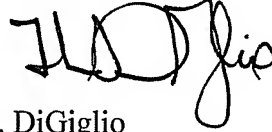
- 1) a morphological correlate suggesting that increased demand on the exocrine pancreas was partially compensated by a multiplication of β cells (pages 26-27);
- 2) the administration of a “whey permeate” as recited in the pending claims resulted in the prevention of the increase of β cell volume and a reduction of the volume of the pancreatic islets (pages 26-27);
- 3) the administration of a “whey permeate” as recited in the pending claims resulted in the lowering of blood lipid values, particularly in a lowering of the triglyceride concentration (pages 23-24);
- 4) the administration of a “whey permeate” as recited in the pending claims resulted in a partially significant lowering of the serum insulin level when applied alone or in combination with further effective substances (pages 28-29);
and
- 5) when rats were treated with a “whey permeate” as recited in the pending claims, the treated rats demonstrated a significantly improved glucose tolerance compared to untreated rats (pages 24-25).

In view of the foregoing, Applicants respectfully submit that claims 1-14 are not obvious over Reimer et al. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Conclusion

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "F. S. DiGiglio", written in a cursive style.

Frank S. DiGiglio
Registration No. 31,346

Scully, Scott, Murphy & Presser, P.C.
400 Garden City Plaza-Suite 300
Garden City, New York 11530
(516) 742-4343
FSD/JRM:reg